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| 09/306,780      | 05/07/1999  | FUMINORI TAKEMURA    | 2084-0046-0D        | 3946             |

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EXAMINER

HINES, JANA A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1645

DATE MAILED: 06/03/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/306,780

Applicant(s)

TAKEMURA ET AL.

Examiner

Ja-Na Hines

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 25-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Amendment Entry***

1 The amendment filed March 11, 2003 has been entered. Claims 25 and 33 have been amended. Claims 25-40 are under consideration in the office action.

### ***Withdrawal of Rejections***

2. The following rejections have been withdrawn in view of applicants' amendments and arguments:

- a) the new matter rejection of claims 33-40 under 35 U.S.C. 112, first paragraph;
- b) the enablement rejection of claims 25-32 under 35 U.S.C. 112, first paragraph;
- and
- c) the rejection of claims 25-32 under 35 U.S.C. 112, second paragraph.

### ***Response to Arguments***

3. Applicant's arguments filed March 11, 2003 have been fully considered but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. The rejection of claims 33-40 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained for reasons of record. There are no steps

Art Unit: 1645

recited in the method for increasing immunological reactivity of a polypeptide in an agglutination immunoassay utilizing bound particles wherein the sole recited step is binding the nucleic acid to the polypeptide using a nucleic acid binding motif.

Claim 33 fails to recite any method steps involved in a method for increasing immunological reactivity of a polypeptide in an agglutination immunoassay. Besides lacking the essential and critical steps as recited above, the claim further fails to recite how to increase the immunological reactivity. As recited above, the missing steps create gaps in the instant invention as claimed. The specification teaches the recited steps, see examples 2-10, including centrifugation steps and the use of sucrose density gradients, however the claims do not positively recite the method steps in the body of claims. The claims do not teach steps that recite how to increase the immunological reactivity as recited by the preamble of the claim. The instant invention cannot be practiced without a complete recitation of the disclosed method steps. There is no correlation between the agglutination and determining an increase of immunological reactivity of a polypeptide. Therefore, the claims are rejected because they fail to recite necessary method steps.

It is known for agglutination assay methods to comprises a reaction medium comprising sample, a plurality of particles having a binding pair member bound to the surface of the particles and an analyte binding partner and detecting the presence of agglutination of the particles in the reaction medium. See Gibbons (US Patent 4,829,011). Without the essential and critical steps recited by the claims, the effects of

Art Unit: 1645

the method for increasing immunological reactivity of a polypeptide in an agglutination immunoassay are largely unpredictable.

Thus the appropriate steps must be recited in order to enable one of skill in the art to practice the invention. Therefore, the recitation lacks essential method steps and thereby results in an unpredictable and unreliable method that cannot be practiced; or in an unpredictable and therefore unreliable correspondence between a method for increasing immunological reactivity of a polypeptide in an agglutination immunoassay. Thus the claims lack support regarding enablement.

Applicants have not recited method steps for a method for increasing immunological reactivity of a polypeptide in an agglutination immunoassay, thus it is not clear that the alleged methods will actually produce agglutination and increase reactivity of the polypeptide. Absent clear demonstration of the methods steps in an agglutination assay, the methods cannot be used in any well-established manner for increasing immunological reactivity of a polypeptide in an agglutination immunoassay. In absence of further guidance from Applicants, the skilled artisan would have to discover what the appropriate method steps, substrates are, the conditions, reagents. Such experimentation requires ingenuity beyond that expected of one of skill in the art. Such need for non-routine experimentation demonstrates that the specification is not enabled for any asserted use or well-established use for bacterial membrane polypeptides. Accordingly, the specification is not enabled for using the alleged method for increasing immunological reactivity of a polypeptide in an agglutination immunoassay in any manner disclosed.

5. The rejection of claims 33-40 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps is maintained for reasons of record. See MPEP § 2172.01. In claim 33 ~~the~~ ~~steps~~, there are no steps that bind the nucleic acid bound polypeptide to the surface of a particle; there is no contact step to contact the antigen with the antibody; there are no reagents named within the method steps, there is no centrifugation step; there is no detection of agglutination; and there are no steps to recite how to determine agglutination. Thus, the claim is rejected for failure to recite any method steps.

6. The rejection of claims 33-35 under 35 U.S.C. 102(b) as being anticipated by Thomas et al., (US Patent 4,749,647) is maintained for the reasons already of record.

The rejection was on the grounds that Thomas et al., teach an agglutination immunoassay or a method for increasing immunological reactivity of a polypeptide in an agglutination immunoassay comprising binding a nucleic acid to a polypeptide, fixing the nucleic acid bound polypeptide on the surface of a particle; contacting the antigen with an antibody and detecting the resultant antigen-antibody complex as claimed.

Applicants assert that Thomas et al., teach an additional polymerization step that the instant invention does not include or require. However, it is the examiner's position that the transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a

Art Unit: 1645

term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"). See also M.P.E.P. 2111.03. Thus, applicant's argument fails to be persuasive, since the claim does not exclude additional polymerization steps.

Applicants assert that the instant invention is distinct because it utilizes binding through a nucleic acid binding motif between the nucleic acid and the polypeptide. The instant specification at page 8 states that the binding motif is known to have the function of binding the nucleic acid to the polypeptide. Thomas et al., teach an interaction between a specific nucleic acid and protein or polypeptide. It is noted that the instant claim methods do not limit the sequence of the binding motif. Moreover, the interaction between the p19 protein [polypeptide] binding to Rous Sarcoma Virus-RNA (RSV-RNA) [nucleic acid] inherently contains binding motif which functions to bind the nucleic acid to the polypeptide since such interaction occurs. Therefore applicants' arguments are not persuasive and the rejection is maintained for the above reasons.

***New Grounds of Rejection***  
***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1645

7. Claims 25-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 25 is unclear. It is unclear how to measure the agglutination of the particles caused by the formation of the antigen-antibody complex. There is no step that teaches how or with what either the antigen or antibody contacts. It is unclear whether the antigen or antibody is being bound to the particles or if the antigen or antibody binds to the polypeptide or nucleic acid. It is unclear what the antigen and antibody are specific binders of. Thus the claims are unclear.

The term "increasing immunological reactivity of a polypeptide" in claim 33 is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. What is the increase being compared to? The metes and bounds of the instant claims are unclear, therefore, the claims are rejected.

### ***Conclusion***

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).




A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines   
May 19, 2003

  
LYNETTE R. F. SMITH  
SUPERVISORY PATENT EXAMINER  
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